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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,362	10/15/2004	Perry J Blackshear	4239-64828-02	3754

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
07/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,362	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2010 and 22 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *28-31, 33-41, 43-46, 49-53, 59, 61 and 63-64* is/are withdrawn from consideration.

5)☒ Claim(s) *18,74 and 75* is/are allowed.

6)☒ Claim(s) *5-9, 11-15,19-21,25-27,65,68,69,72 and 76* is/are rejected.

7)☒ Claim(s) *10 and 77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 5-15,18-21,25-31,33-41,43-46,49-53,59,61,63-65,68,69,72 and 74-77.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 10/22/2009 and 2/03/2010, have been entered.

Claims 5-15, 18-21, 25-31, 33-41, 43-46, 49-53, 59, 61, 63-65, 68-69, 72 and new claims 74-77 are pending in the present application.

Applicants also elected previously the following species: (a) SEQ ID NO:8 (corresponding SEQ ID NO:37) as a species of an encoded polypeptide; (b) SEQ ID NO:11 as a species of a promoter; and (c) SEQ ID NO:33 and SEQ ID NO: 34..

Claims 7, 14, 28-31, 33-41, 43-46, 49-53, 59, 61 and 63-64 were withdrawn previously because they are directed to non-elected invention and non-elected species. In light of currently amended claims 7 and 14 which contain elected species, these amended claims are rejoined for examination.

Accordingly, amended claims 5-15, 18-21, 25-27, 65, 68-69, 72 and new claims 74-77 are examined on the merits herein with the above elected species.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This is because the nucleic acid molecule in claim 7 which is dependent on claim 18 is not necessarily comprising SEQ ID NO: 8 (e.g., 95 % identical to SEQ ID NO: 8).

Claim 77 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 74. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The isolated nucleic acid molecule in both claims 74 and 77 encode a RFX4_v3 polypeptide comprising SEQ ID NO: 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Amended claims 5-9, 11-14, 25-26, 65 and 68-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US 6,812,339; IDS). ***This is a new ground of rejection.***

It is noted that the instant specification defines the term "sequence identity" to mean that two polynucleotide sequences are identical over the window of comparison (page 16, lines 1-2); and the term "reference sequence" to mean a defined sequence used as a basis for a sequence comparison; a reference sequence may be a subset of a larger sequence, for example, as a segment of a full-length cDNA sequence given in a sequence listing or may comprise a complete gene sequence (page 15, lines 16-20). Accordingly, the limitations "an amino acid sequence at least 99% identical to SEQ ID NO: 8"; "an amino acid sequence at least 95% identical to SEQ ID NO: 8"; "nucleic acid sequence is at least 95% identical to SEQ ID NO: 37"; "the nucleic acid sequence is at least 99% identical to SEQ ID NO: 37" are not necessarily limited to a comparison between an amino acid sequence or a nucleic acid sequence over a full-length SEQ ID NO: 8 (reference sequence) and a full-length SEQ ID NO: 37 (reference sequence), respectively. Therefore, the following rejection is applied.

With respect to the elected species, Venter et al disclosed genomic nucleotide sequences, transcript sequences including SEQ ID NO:416, encoded amino acid sequences that contain single nucleotide polymorphisms (see at least Summary of the Invention; col. 5, line 60 continues to line 25 of col.6; col. 9, line 53 continues to line 62). The nucleotide sequence of SEQ ID NO: 416 is 72.3% identical (with 99.3% best local similarity) to the full-length nucleotide sequence of SEQ ID NO: 37 of the present invention, and having at least 100% identical nucleotides 43-1563 of SEQ ID NO: 37. Please note that the term "RFX4_v3 polypeptide" is defined by the instant specification to include fragments of the RFX4_v3 sequence as well as other domains within the full-

length RFX_v3 polypeptide (see at least page 10, lines 28-34 of the instant specification). Venter et al further teach that the disclosed nucleic acid molecules may be double stranded molecules and include both a protein encoding strand (sense strand) as well as a complementary nucleotide sequence comprising a sequence complementary to the protein encoding strand or anti-sense strand (col. 8, lines 1-51). The isolated nucleic acid molecule can be cloned into an expression vector, introduced into a host cell such as a bacterial cell, a yeast cell or a mammalian cell for purifying the encoded variant protein (col. 11, lines 40-50; col. 19, lien 39 continues to line 6 of col. 23). Venter et al further disclose that the variant protein can be used in assays to determine the biological activity of the variant protein as well as for raising antibodies (col. 32, line 65 continues to line 18 of col. 33). It is noted that the isolated variant transcript having SEQ ID NO: 416 has been mutagenized *in vivo*; and that at least a RFX4-v3 activity is the ability to be recognized by a RFX4-v3 specific antibody. With respect to claim 26, a DNA comprising SEQ ID NO:416 would also inhibit the binding of the polynucleotide of claim 15 to its complementary sequence since it already has at least 100% identical nucleotides 43-1563 of SEQ ID NO: 37. There is no requirement whatsoever that a nucleic acid molecule in a composition of claim 26 has to have any of nucleotides 1-42 of SEQ ID NO: 37.

The teachings of Venter et al meet all the limitation of the instant claims as broadly written. Accordingly, the reference anticipates the instant claims.

Claims 5-8, 11, 14-15, 19, 26-27, 65, 68-69, 72 and 76 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Acc. No. BB611282.1 (Oct 26, 2001). ***This is a new ground of rejection.***

The GenBank Accession No. BB611282.1 is a 591 nucleotide cloned cDNA molecule that has **at least** nucleotide residues 432-473 that are identical to nucleotides 1-42 of SEQ ID NO: 37. In light of a broad scope encompassing by the terms "identical to SEQ ID NO: 8" as already discussed above, the GenBank BB611282.1 cDNA molecule meets every limitation of the claims as broadly written.

Accordingly, the reference anticipates the instant claims.

Claims 15, 19-21 and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al. (US 7,560,542). ***This is a new ground of rejection.***

Andersen et al disclose an isolated nucleic acid molecule comprising SEQ ID NO: 65,529 which is a 386 nucleotide molecule that has nucleotides 129-144 that are identical to nucleotides 16-31 of SEQ ID NO: 37 (see at least Summary of the Invention and SEQ ID NO: 65,529). Andersen et al further disclosed that the nucleic acid molecule is operably linked to an exogenous promoter for expression in a suitable bacterial or eukaryotic host, including in a plant cell (see at least Summary of the Invention; col. 16, line 46 continues to line 3 of col. 17).

Accordingly, the teachings of Andersen et al meet the limitation of the claims as broadly written. Therefore, the reference anticipates the instant claims.

To overcome the above prior art rejections, the Examiner suggests at least using the following limitations in appropriate claims: "an amino acid sequence ***at least 99% identical to the amino acid sequence of SEQ ID NO: 8****"; "an amino acid sequence* ***at least 95% identical to the amino acid sequence of SEQ ID NO: 8****"; "nucleic acid sequence is* ***at least 95% identical to the nucleotide sequence of SEQ ID NO: 37****"; "the nucleic acid sequence is* ***at least 99% identical to the nucleotide sequence of SEQ ID NO: 37****". Additionally, with respect to claim 35 please also amend to "a wild-type nucleic acid sequence* ***having*** *SEQ ID NO: 37, SEQ ID NO: 38, or SEQ ID NO: 39". For claim 26, there must be additional structural limitation for a nucleic acid molecule in the composition of claim 26 in order to overcome the above prior art.*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Knoll et al (US 6,828,097) disclosed a test genomic sequence of SEQ ID NO: 25 which is a 833 nucleotide molecule that has nucleotides 227-243 that are identical to nucleotides 6-22 of SEQ ID NO: 37 (col. 15, line 2 and SEQ ID NO: 25).

Conclusion

Claims 18 and 74-75 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/
Primary Examiner, Art Unit 1633